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10/500,646	10/12/2004	Claude Mabilat	120162	2871

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EXAMINER	
MYERS, CARLA J	
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1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,646	MABILAT ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-29* is/are pending in the application.

4a) Of the above claim(s) *19,20,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed January 31, 2008. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. In particular, the previous rejection of the claims under 35 U.S.C. 112, first paragraph, written description, has been obviated by the amendments to the claims. The rejection of claims 1, 2, 4 and 9 under 35 U.S.C. 102(b) as being anticipated by Fodor et al has been obviated by the cancellation of these claims and the amendments to the newly added claims to recite that the nucleic acid fraction is contacted with a combination of oligonucleotides respectively comprising SEQ ID NO: 1-232 and 242-276. While Fodor et al teach a method for detecting nucleic acids comprising contacting a nucleic acid fraction with a combination of all possible 10-mer probes, Fodor does not teach contacting a nucleic acid fraction with a combination of oligonucleotides respectively comprising the sequences of SEQ ID NO: 1-232 and 242-276.

This action contains new grounds of rejection necessitated by Applicant's amendments to the claims and is made final.

Election/Restrictions

2. This application contains claims 19, 20, 28 and 29 drawn to an invention nonelected with traverse in the reply filed on June 13, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

It is noted that In the reply of June 13, 2007, Applicant elected with traverse of Group I and the combination of sequences of SEQ ID NO: 1-232 and 242-261. However, claims 19 and 20 are drawn to claims which further require the use of the nucleic acids of SEQ ID NO: 24-241 and 272-276. These nucleic acids are not included in the elected combination and claim 18, from which claims 19 and 20 depend, is not currently allowable. Thereby, claims 19 and 20 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 28 and 29 are withdrawn from consideration since these claims are drawn to the non-elected subject matter of invention II. In the reply filed on January 31, 2008, Applicant states that claims 28 and 29 should be examined with the elected invention because the combination of nucleic acids claimed in claims 28-29 share the same technical feature as that of claims 18-27. However, claim 28 does not recite that the combination of oligonucleotides are isolated and the claim recites the terminology of "comprising" thus allowing for the inclusion of flanking nucleic acid sequences. It is also noted that the specification does not define the term "oligonucleotide" as being limited to any particular length. The claims also include nucleic acids sharing any level of sequence complementarity with SEQ ID NO: 1-232 and 242-261. Accordingly, the subject matter of claim 28 was known in the art at the time the invention was made since the claim encompasses unisolated nucleic acids present in cells of organisms, wherein the nucleic acids comprise SEQ ID NO: 1-232 and 242-261 or sequences complementary thereto (i.e., the total combination of genetic material present in organisms). Thereby, there is no special technical feature linking the elected invention

of group I and the nonelected invention of group II, as would be required to show unity of invention.

Thus, claims 18, and 21-27 have been examined herein. Claims 19, 20 and 28-29 are withdrawn from consideration as being drawn to a non-elected invention.

New Claim Objections

3. Claims 21-25 are objected to because the claims reference "field <213> of SEQ ID NO: 1-232 and 242-261." Claims which recite figures or tables are only permitted in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into a claim. However, it is not appropriate to reference particular fields from the Sequence Listing in the claims. See MPEP 2173.05(s):

> Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112 second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-25 are indefinite over the recitation of "taxonomic group listed in field <213>" because filed <213> of the Sequence listing recites an organism (i.e., a genus and species) but does not recite a taxonomic group. Thereby, it is unclear as to what is intended to be encompassed by the "taxonomic group listed in field <213>."

New Grounds of Rejection

Claim Rejections - 35 USC § 112 – New Matter

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-25 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not provide basis for the recitations in newly added claims 21-25 of a method further comprising determining whether the sample contains a nucleic acid fraction from any organism belonging to a taxonomic group listed in field <213> for SEQ ID NO: 1-

232 and 242-261 (claim 21); determining which taxonomic group listed in field <213> a nucleic acid fraction belongs to (claim 22); determining whether a sample does not contain a nucleic acid fraction from the taxonomic groups listed in field <213> (claim 23); determining whether a sample contains a nucleic acid fraction from one or more taxonomic groups listed in field <213> (claim 24); or determining whether each of the taxonomic groups listed in field <213> are absent from a sample (claim 25).

In the response of January 31, 2008, Applicants generally state that the specification and claims provide support for the above amendments. However, the specification as originally filed does not appear to provide support for the embodiments recited above. In particular, the specification provides support only for the concept of determining an original animal species in a sample wherein the original animal species is detected using the probes of SEQ ID NO: 1-232 and 242-261 and detecting hybridization of the probes to a target nucleic acid sequence as indicative of the presence of an animal species. The specification does not appear to provide basis for the distinct concept of using the probes of SEQ ID NO: 1-232 and 242-261 to detect the presence or absence of one or all taxonomic groups to which the organisms in field <213> belong. The specification also discloses the use of the non-elected oligonucleotides of SEQ ID NO: 240, 241 and 272-276 to determine the taxonomic class of an organism present in a nucleic acid sample. The specification does not, however, disclose the use of the elected oligonucleotides of SEQ ID NO: 1-232 and 242-261 to the

presence or absence of any taxonomic group or all taxonomic groups for the organisms recited in fields <213> of the respective sequences, including taxonomic groups of phylum, subphylum, order, suborder, family, etc.

Additionally, the claims do not recite any steps regarding how the determination of the presence or absence of a taxonomic group is made. Thereby, the claims include any means for determining the identity of the taxonomic group or the presence or absence of a taxonomic group, such as by using alternative probes or primers, by sequencing nucleic acids present in the sample or by performing biological activity assays using the nucleic acids or products encoded thereby. However, the specification as originally filed does not provide basis for the use of any method or means to determine whether a sample contains or does not contain a nucleic acid fraction from any taxonomic group listed in field <213> or for any method or means to identify the taxonomic group to which a nucleic acid belongs.

Regarding claims 23 and 24, the specification also does not appear to provide support for the concept of determining whether a sample contains or does not contain a nucleic acid fraction from one or more predetermined taxonomic groups selected from the groups recited in field <213> for SEQ ID NO: 1-232 and 242-261.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112 - Enablement

7. Claims 18 and 21-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is noted that this rejection was originally set forth in the Office action of August 31, 2007 and has been modified to address the amendments to the claims.

The following factors have been considered in formulating this rejection (*In re Wands,* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Breadth of the Claims:

The claims are drawn to methods comprising contacting a nucleic acid fraction from a sample with a combination of oligonucleotides respectively comprising the sequences set forth in SEQ ID NO: 1-232 and 242-261 or "full length complementary sequences thereof." The specification indicates that complementary sequences may include sequences that hybridize at 20 to 70°C in a saline solution of 0.5M to 1M to the probes of SEQ ID NO: 1-232 and 242-261. However, the specification does not provide

a clear definition for the term "complementary." As such the claims read on nucleic acids which comprise sequences sharing low levels, such as 30% or 40% etc, complementarity with SEQ ID NO: 1-232 and 242-261 or with portions of SEQ ID NO: 1-232 and 242-261, as long as the oligonucleotides comprise sequences of the same length as SEQ ID NO: 1-232 and 242-261. The specification teaches that the methods are to be used to detect the occurrence of original animal species in a biological sample. Accordingly, the claims encompass methods which require the use of a phenomenally large genus of oligonucleotides for the detection of original animal species, wherein the nucleic acid sequences are very broadly defined as having limited sequence complementarity with all or a portion of SEQ ID NO: 1-232 and 242-261 and are not defined in terms of their specific functional properties (i.e., the particular organisms to which the nucleic acid sequences hybridize under a certain set of hybridization conditions).

Additionally, claims 21-25 are drawn to methods which further comprise determining whether the sample contains a nucleic acid fraction from any organism belonging to a taxonomic group listed in field <213> for SEQ ID NO: 1-232 and 242-261 (claim 21); determining which taxonomic group listed in field <213> a nucleic acid fraction belongs to (claim 22); determining whether a sample does not contain a nucleic acid fraction from the taxonomic groups listed in field <213> (claim 23); determining whether a sample contains a nucleic acid fraction from one or more taxonomic groups listed in field <213> (claim 24); or

determining whether each of the taxonomic groups listed in field <213> are absent from a sample (claim 25).

Nature of the Invention:

The claims are drawn to methods of nucleic acid hybridization to determine the taxonomic group to which an organism belongs. The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F. 3d 1316, 1330 (Fed Cir. 2001).

Teachings in the Specification and State of the Art:

The specification discloses the nucleic acids consisting of SEQ ID NO: 1-232 and 242-261. The sequence listing identifies the species from which the nucleic acids were derived. However, the specification itself does not provide any information regarding the specificity of the nucleic acids. No data is provided, for instance, showing that any particular nucleic acid hybridizes to one or more "original animal species." No information is provided as to the hybridization conditions that would be required to use the sequences of SEQ ID NO: 1-232 and 242-261 to detect specific animal species or taxonomic groups. For example, SEQ ID NO: 1 was obtained from Anas platyrhynchos. However, the specification does not teach if SEQ ID NO: 1 hybridizes only to A. platyrhynchos (and under what conditions) and distinguishes this species from other Anas species or if SEQ ID NO: 1 also cross hybridizes with other Anas species or other non-Anas species.

Given the limited information provided in the specification, it cannot be ascertained as to whether the specification teaches any particular nucleic acids consisting of a sequence that hybridizes specifically to one animal species and which distinguishes that one animal species from other animal species.

For example, SEQ ID NO: 9 is characterized in the sequence listing as being obtained from Cairina moschata (Muscovy duck). However, the sequence of SEQ ID NO: 9 is also present in, and therefore will cross-hybridize to and detect, Siganus rivulatus (rabbitfish; GenBank Accession No. AY24940):

```
Qy          1 AACCTGCACGCCAATG 16
              ||||||||||||||||
Db        110 AACCTGCACGCCAATG 95
```

SEQ ID NO: 9 is also present in, and therefore will cross-hybridize to and detect, Gerrhosaurus flavigularis (lizard; GenBank Accession No. AY17383):

```
Qy          1 AACCTGCACGCCAATG 16
              ||||||||||||||||
Db        229 AACCTGCACGCCAATG 244
```

Similarly, while SEQ ID NO: 8 is characterized as being obtained from Anser anser, this sequence is also present in, and therefore will cross-hybridize to and detect, Anser albifrons (GenBank Accession No. AY072598):

```
Qy          1 CACTTCACTCGCCTTCTC 18
              ||||||||||||||||||
Db         77 CACTTCACTCGCCTTCTC 94
```

SEQ ID NO: 8 also shares 94% identity with, and therefore will cross-hybridize to and detect, Enterobacter cloacae (GenBank Accession No. AEH54479):

```
Qy          1 CACTTCACTCGCCTTCTC 18
```

```
                || ||||||||||||||||
Db          636 CAATTCACTCGCCTTCTC 619
```

Further, nucleotides 1-17 of SEQ ID NO: 8 are present in, and therefore will cross-hybridize to and detect, Mus musculus (GenBank Accession No. BB278453):

```
Qy            1 CACTTCACTCGCCTTCT 17
                |||||||||||||||||
Db           57 CACTTCACTCGCCTTCT 73
```

Regarding SEQ ID NO: 4, this nucleic acid shares 91.7% identity with, and therefore will cross hybridize with Pimephales promelas (GenBank Accession No. DT268277):

```
Qy            1 GACACATCCCTTGCTTTCTCCTCA 24
                |||||||||||||| ||||||| ||
Db          422 GACACATCCCTTGGTTTCTCCCCA 399
```

Regarding SEQ ID NO: 3, this nucleic acid shares 88% identity with, and therefore will cross hybridize with Oryzias latipes (Japanese killfish; GenBank Accession No. DE063816):

```
Qy            7 TCTCTGCTCGCCATCTGCCTGGCCACACAAAT 38
                |||||||| |||||||| ||  |||||||||
Db          188 TCTCTGCTCTCCATCTGCTTGAACACACAAAT 219
```

Regarding SEQ ID NO: 2, nucleotides 1-18 are 100% identical to sequences in the Schistosoma mansoni genome and therefore this sequence and 5mer fragments thereof will hybridize to Schistosoma mansoni DNA (GenBank Accession No. DX987659):

```
Qy            1 GTAATCCTACTGCTCACT 18
                ||||||||||||||||||
```

```
Db          48 GTAATCCTACTGCTCACT 31
```

Regarding SEQ ID NO: 1, this sequence shares 94% identity to sequences in the human genome and therefore this sequence and 5mer fragments thereof will hybridize to human DNA (GenBank Accession No. ADR07925):

```
Qy           1 CTCCTACTGGCTATGCAC 18
               ||||| ||||||||||||
Db        1592 CTCCTGCTGGCTATGCAC 1609
```

Additionally, the sequence of SEQ ID NO: 1 is identical to sequences present in Aedes aegypti (yellow fever mosquito; GenBank Accession No: DV296868). Therefore, SEQ ID NO: 1 will cross-hybridize with and detect nucleic acids present in a sample that are from Aedes aegypti:

```
Qy           1 CTCCTACTGGCTATGCAC 18
               ||||||||||||||||||
Db          81 CTCCTACTGGCTATGCAC 98
```

The specification also teaches the primers of SEQ ID NO: 240 and 241 which are universal primers that amplify all animal species. The specification further teaches a number of "signature sequence" consisting of SEQ ID NO: 23-239 and 262-271. However, the present claims are not directed to these sequences, but rather are directed to variants of SEQ ID NO: 1-232 and 242-261. Further, the recited sequences do not appear to be specific for only a single animal species, but rather also hybridize with other species within the same or a different genus. For example, the specification (page 50) discloses the sequence of SEQ ID NO: 262 and indicates that this sequence was obtained from Bos Taurus and hybridizes to sequences within mammals. For

instance, the sequence of SEQ ID NO: 262 is identical to a sequence present in Silka deer (GenBank Accession No. AY245522):

```
Qy          1 CTAATCCTACAAATC 15
              ||||||||||||||| 
Db          4 CTAATCCTACAAATC 18
```

and Puma (GenBank Accession No. AF499775):

```
Qy          1 CTAATCCTACAAATC 15
              ||||||||||||||| 
Db         26 CTAATCCTACAAATC 40
```

The Predictability or Unpredictability of the Art and Degree of Experimentation:

The prior art acknowledges the unpredictability in modifying the nucleotide sequence of a nucleic acid probe. Modification of even a single nucleotide within a nucleic acid sequence can significantly alter the specificity of hybridization of that sequence. This finding is evidenced by the teachings above wherein the change at nucleotide position 3 within SEQ ID NO: 8 results in a probe that cross-hybridizes with Enterococcus cloacae and wherein the deletion of a terminal nucleotide results in a probe that cross-hybridizes with Mus musculus. The specification does not provide any information as to regions of SEQ ID NO: 1-232 and 242-261 which are critical for functional activity and for maintaining the hybridization specificity of the probe. It is unpredictable as to which nucleotides can be inserted or deleted or substituted within SEQ ID NO: 1-232 and 242-261 without altering the specificity of the probe. It is also unpredictable as to how adding nucleotides of any identity or length to SEQ ID NO: 1-232 and 242-261 or fragments thereof will effect the functional properties of the resulting nucleic acids. Most importantly, it remains highly unpredictable as to how the combination of nucleic acids of SEQ ID NO: 1-232 and 242-261 can be used to

determine an original animal species or to identify a taxonomic group to which an organism belongs since these nucleic acids appear to cross-hybridize with other species and the specificity of hybridization of these nucleic acids has not been disclosed in the specification.

Amount of Direction or Guidance Provided by the Specification:

Regarding claims 21-25, the specification does not provide any specific guidance as to how to predictably use the nucleic acids of SEQ ID NO: 1-232 and 242-261 to determine if a sample contains or does not contain an organism belonging to one or more of the "taxonomic groups" listed in field <213> of the sequence listing for SEQ ID NO: 1-232 and 242-261. In field <213>, the sequence listing appears to provide the species and genus for the organism from which the nucleic acid was isolated. However, the specification does not provide any information regarding a taxonomic group which can be detected using the nucleic acids of SEQ ID NO: 1-232 and 242-261. Taxonomic groups include phylum, subphylum, class, subclass, genus and subgenus etc. Yet, no information is provided in the specification regarding the specificity of the nucleic acids for these or other taxonomic groups.

Regarding the recitation of "full-length complementary sequence," the specification does not provide any guidance as to how to use oligonucleotides sharing minimal complementarity with SEQ ID NO: 1-232 and 242-261 or portions thereof in a manner consistent with the teachings in the specification - that is to detect the presence of a nucleic acid of an organism present in a biological sample. As discussed above, the sequence listing identifies the source of the nucleic acids, yet, the specification does not

teach which animal species the probes hybridize to and the conditions under which such hybridization occurs. The specification fails to provide guidance as to how to make and use variants of the SEQ ID NO: 1-232 and 242-261 (i.e., complementary sequences) to detect the presence of nucleic acids from animal species present in a biological sample. Again, modification of the nucleic acids by the substitution, addition or deletion of even 1 nucleotide significantly alters the specificity of hybridization of the nucleic acids. No guidance is provided in the specification as to which nucleotides within SEQ ID NO: 1-232 and 242-261 can be added, deleted or substituted and what will be the result of such modifications. Also, no guidance is provided as to what nucleotides and the number of the nucleotides that can be added to the terminus of SEQ ID NO: 1-232 and 242-261 and 5mer fragments thereof and no guidance is provided as to how to use the resulting nucleic acids to detect particular animal species.

While the artisan could generate a significantly large genus of nucleic acids in which nucleotides of any identity are added to the 5' or 3' terminus of SEQ ID NO: 1-232 and 242-261 and fragments thereof or in which any number of nucleotides within SEQ ID NO: 1-232 and 242-261 are mutated via substitution, addition or deletion, and then assay each of these nucleic acids to try to determine their specificity of hybridization under particular conditions of hybridization, such trial-by-error experimentation is considered to be undue. Providing methods for searching for additional nucleic acids and trying to determine the function of the resulting nucleic acid is not equivalent to teaching how to make and use specific nucleic acids.

Working Examples:

The specification teaches only the nucleic acid of SEQ ID NO: 1-232 and 242-261. In field <213>, the Sequence Listing recites the source of these nucleic acids. However, the specification does not provide any examples of using these nucleic acids to determine whether a sample contains or does not contain a nucleic acid fraction from an organism belonging to any taxonomic group to which the organisms listed in field <213> belong. The specification also does not provide any examples of using SEQ ID NO: 1-232 and 242-261 to determine whether a sample contains or does not contain a nucleic acid fraction from one or more predetermined taxonomic groups selected from the taxonomic groups listed in field <213> for SEQ ID NO: 1-232 and 242-261. Additionally, the specification does not exemplify a representative number of variants of SEQ ID NO: 1-232 and 242-261 and methods of using said variants to detect original animal species, wherein the variants may share minimal (e.g., 30% or 40%) complementarity with SEQ ID NO: 1-232 and 242-261 or with portions thereof while comprising a sequence of the same length as SEQ ID NO: 1-232 and 242-261.

Conclusions:

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the

art as well as the predictability in the art. Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the specification does not disclose the specificity of any of the hybridization probes consisting of SEQ ID NO: 1-232 and 242-261 and does not provide sufficient guidance to enable the skilled artisan to use these oligonucleotides to determine if a sample contains a nucleic acid from an organism belonging to a taxonomic group of field <213> or to determine which taxonomic group listed in field <213> an organism belongs to. Further, the claims do not bear a reasonable correlation to the scope of enablement because while the specification teaches nucleic acids consisting of SEQ ID NO: 1-232 and 242-261, the claims broadly encompass the use of and detection of millions upon millions of possible variants of these nucleic acids, in which the complete structure and the functional properties of the nucleic acids are not defined. Accordingly, although the level of skill in the art of molecular biology is high, given the lack of disclosure in the specification and in the prior art, it would require undue experimentation for one of skill in the art to make and use the broadly claimed invention.

Response to Remarks:

In the response, Applicants do not specifically traverse the rejection. Applicants state only that the claims comply with the enablement requirement. However, the newly added claims 18 and 21-27 do not meet the enablement requirements for the reasons set forth above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Carla Myers/

Primary Examiner, Art Unit 1634